

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE AG,)	
ALCON, INC. and)	REDACTED –
ALCON RESEARCH, LTD.,)	PUBLIC VERSION
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 06-234-SLR
)	
TEVA PHARMACEUTICALS USA, INC.,)	
)	
Defendant.)	

PLAINTIFFS' POST-TRIAL REPLY BRIEF ON INFRINGEMENT

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Teva's non-infringement argument requires the Court to ignore the bedrock principle that claims are construed through the eyes of the person of ordinary skill in the art ("POOS"). It asks this Court to disregard the black-letter law that whether a patentee has "redefined" a claim term must be assessed from the perspective of the POOS after consideration of the patent as a whole. And it further urges the Court overlook undisputed evidence that (1) "moxifloxacin" had a clear, established meaning to the POOS in September 1998 and (2) the POOS would not have read the '830 patent to redefine moxifloxacin. In light of this overwhelming record, the suggestion that Teva's product does not infringe is baseless. That Teva would have the audacity to ask for an award of fees based on such a suggestion is simply stunning. The record is clear: moxifloxacin in the '830 patent has its ordinary meaning. Teva's product therefore infringes.

I. TEVA APPLIES THE WRONG ANALYTICAL FRAMEWORK

A. Claims Are Construed Through the Eyes of the POOS

Phillips makes clear that claims are to be read from the perspective of the POOS.

Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*) (claim term has the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention"). Seeking to avoid the uncontested evidence regarding how the POOS would understand "moxifloxacin," Teva argues that the POOS is irrelevant where the patentee serves as his own lexicographer. D.I. 108 (Teva Infringement Br.) at 2-3. That puts the cart before the horse—whether the patentee has redefined a term is assessed from the standpoint of the POOS. See D.I. 93 (Alcon Infringement Br.) at 9; see also *Innova/Pure Water, Inc. v Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) (cited by Teva) (to redefine a term, patentee must "set out the different meaning in the specification in a manner sufficient to give one of ordinary skill in the art notice of the change from ordinary meaning") (emphasis added).

Teva attempts to elide this clear rule, positing that the critical issue is whether the

patentee has informed the “public” of the redefinition. D.I. 108 at 2-3, 12-13. But the “public notice” issue is whether the patent—a public document—makes clear to the person of ordinary skill that the patentee is redefining a term, not whether the general public having no background in the area or an infringer’s trial lawyers would read a particular sentence plucked out of a specification as an express definition. *See, e.g., Miken Composites, L.L.C. v. Wilson Sporting Goods Co.*, 515 F.3d 1331, 1338 (Fed. Cir. 2008) (evaluating whether the patentee provided “notice to the public—i.e., those of ordinary skill in the art” that a claim term differed from its ordinary meaning); *Nystrom v. Trex Co.*, 424 F.3d 1136, 1145 (Fed. Cir. 2005) (same).

B. A Redefinition Must Be Clear from the Patent as a Whole

Teva’s non-infringement argument focuses exclusively on one snippet of the ’830 patent that Teva asserts contains an express definition. D.I. 108 at 2-3. The law is clear, however, that the Court must consider the specification as a whole to determine if a patentee has redefined a claim term. D.I. 93 at 9; *Phillips*, 415 F.3d at 1324 (courts should consider the entirety of the evidence in construing a claim term and may do so in any sequence). This is true even if there is language that could be argued to be in definitional format.¹ For example, in *Abbott Laboratories v. Andrx Pharmaceuticals, Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007), the defendant argued that the patentee defined a term by using allegedly definitional language (the word “is”). The court disagreed, holding that, in view of the intrinsic and extrinsic evidence as a whole “from the point

¹ *Sinorgchem Co. v. ITC*, 511 F.3d 1132 (Fed. Cir. 2007), cited by Teva, is consistent with this approach. The court there did not stop its analysis upon encountering arguably definitional language, but rather examined multiple parts of the specification to assess whether there had been a redefinition. *Id.* at 1136-38. Other cases cited by Teva support the same principle. *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1361-62 (Fed. Cir. 2008) (examining claim term not “in isolation but in a larger context that clarifies its meaning”); *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1361-64 (Fed. Cir. 2007) (finding redefinition only after concluding that intrinsic record consistently pointed away from ordinary meaning); *Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1330-31 (Fed. Cir. 2003) (specification consistently pointed away from ordinary meaning).

of view of one of skill in the art,” this language did not define the claim term. *Id.* at 1210-11.

II. THE INVENTORS DID NOT REDEFINE “MOXIFLOXACIN”

Grasping at straws, Teva points to isolated excerpts of the evidence as purporting to show that the '830 patent redefined “moxifloxacin” to be a different compound having a 3-methyl group. Teva presented no evidence that the POOS would read the patent in that manner. In fact, far from establishing that the inventors redefined moxifloxacin, the evidence consistently demonstrates that “moxifloxacin” in claim 1 carries its ordinary meaning.

A. The “New Class of Antibiotics” Includes Moxifloxacin

In arguing that the '830 patent redefined “moxifloxacin” to mean some completely new and different compound, Teva seizes on language stating that the invention involves using a “new class of antibiotics.” Teva reasons that “moxifloxacin” as used in the specification could not be a quinolone because “the ‘new class’ of drugs to be formulated must not be members of the prior art, quinolone, class of antibiotics.” D.I. 108 at 4. That makes no sense at all. The “new class” referenced in the '830 patent is the compounds of formula (I). *See* PTX 5, Col. 1, ll. 18-19 (“The compositions and methods of the invention are based on the use of a new class of antibiotics.”); Col. 2, ll. 48-50 (“The antibiotics used in the compositions and methods of the present invention have the following formula: (I)”); Col. 5, ll. 55-58 (“compositions of the present invention will contain one or more compounds of formula (I)”). Teva acknowledges that the compounds in formula (I) are all quinolones, D.I. 108 at 5 (referring to originally filed claim 1), thereby refuting any notion that the patent is directed to using a class of compounds other than quinolones.

Ignoring the patent’s clear disclosure that the “new class” is the quinolone compounds of formula (I), Teva urges the Court to find that the “new class” refers to only one compound that is

neither a quinolone nor part of Formula (I).² Teva's argument also requires the Court to believe that in selecting a name for a different compound lacking a 3-carboxylic acid, the inventors chose to call it (of all things) "moxifloxacin"—the internationally recognized name for a specific 3-quinolone carboxylic acid having a remarkably similar structure, even though the suffix "oxacin" was known to refer to compounds with a 3-carboxylic acid, *see* D.I. 93 at 7-8, 11-12, the very substituent of moxifloxacin missing from the "new" compound.

Teva presented no evidence that the POOS would read the '830 patent in such an illogical way, and the evidence showed that the POOS would not. Indeed, the record establishes that the entire context of the '830 patent has to do with the use of quinolones. Tr. 103:12-104:11 (Taylor). As such, the POOS would know that the phrase "new class of antibiotics" refers to quinolones having novel bicyclic substituents at the 7-position, D.I. 93 at 11 n.6; *see* Tr. 1030:14-1031:6 (Zhanel) (correct to refer to quinolones in the patent as a "new class").

The '830 patent reinforces this understanding by expressly referring the reader to the '942 patent for details about moxifloxacin's structure. PTX 5, Col. 3, ll. 49-51.³ The '942 patent discloses quinolones with the aforementioned bicycle, including moxifloxacin. PTX 3, Claim 1. Also, the '942 patent is entitled "7-(1-Pyrrolidinyl)-3-Quinolone- and Naphthyridone-Carboxylic Acid Derivatives as Antibacterial Agents and Feed Additives"—making clear that it relates to 3-quinolone carboxylic acids. PTX 3; Tr. 80:15-24 (Taylor). Indeed, every compound in the '942 patent has a 3-carboxylic acid or precursor thereof, an immutable feature of quinolones. Tr. 80:1-24 (Taylor); D.I. 108 at 5. Thus, the '942 patent makes clear to the POOS that the structure at Column 3 of the '830 patent contains a typographical error, *i.e.*, it omits the 3-carboxylic acid.

² The patent repeatedly indicates that moxifloxacin is a compound of formula (I). *See infra* at 6.

³ Looking to the '942 patent for information about moxifloxacin's structure is thus hardly a "litigation-inspired, connect-the-dots trek" to "unrelated" extrinsic evidence. *See* D.I. 108 at 6-7.

Teva has no explanation for why the '830 patent would specifically refer the reader to the '942 patent for details about moxifloxacin, including its structure, if it were not a quinolone whose structure was in the '942 patent. Indeed, the reference to the '942 patent immediately after the structure in Column 3 is sufficient to inform the POOS that "moxifloxacin" was not redefined. *See Abbott Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1354-55 (Fed. Cir. 2003) (no redefinition where portion of passage provided "ordinary meaning" and another provided "different definition"); *see also* D.I. 93 at 11. Teva therefore tries to change the subject by arguing that the '830 patent does not formally incorporate the '942 patent, because it does not "clearly indicate" where the details concerning moxifloxacin are located in the '942 patent. D.I. 108 at 9. Not only is this beside the point—the '830 patent clearly directs the POOS to the '942 patent for details about moxifloxacin and thus informs the POOS as to the term's meaning, whether or not the latter patent is "incorporated"—but it is also legally wrong. A patentee need not provide column and line numbers to incorporate parts of a patent by reference; rather, it need only specify what information is being incorporated. Indeed, the very case on which Teva relies held that language nearly identical to that found in the '830 patent properly incorporated the indicated information. *See* D.I. 108 at 9; *Zenon Envtl., Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1379 (Fed. Cir. 2007) (statement that "Further details relating to the construction and deployment of a most preferred skein are found in the" incorporated patent incorporated details relating to construction and deployment). Likewise, the '830 patent incorporates details concerning, *inter alia*, the "structure . . . of moxifloxacin." PTX 5, Col. 3, ll. 49-51; Tr. 120:2-121:19 (Taylor) (POOS would know compound in '942 patent claim 1 was moxifloxacin).

B. Moxifloxacin Is Part of Formula (I)

Teva asserts that even though the '830 patent discloses a general formula (I) with a 3-carboxylic acid and labels moxifloxacin the "most preferred" compound, moxifloxacin is the

only compound in the patent that is not within formula (I). There is no evidence to support that illogical conclusion. To the contrary, the '830 patent expressly provides that moxifloxacin is part of formula (I), stating: "[f]urther details regarding . . . Moxifloxacin and other compounds of formula (I)" can be found in the '942 patent. PTX 5, Col. 3, ll. 49-51; *see also* D.I. 93 at 12-13. The patent also states (1) that "[t]he antibiotics used in the compositions and methods of the present invention have the following formula: (I)," PTX 5, Col. 2, ll. 48-50; and (2) that the "compositions of the present invention will contain one or more compounds of formula (I)," Col. 5, ll. 55-57. Those statements do not make sense unless moxifloxacin is part of formula (I).⁴

The file history reinforces this point. Although Teva mentions the originally-filed claims, it glosses over the fact that original claim 6 was to compositions comprising moxifloxacin, and that this claim was dependant from a claim to compositions of compounds of formula (I) (claim 1). PTX 6 at BA001-1583-85. The relationship between those claims requires moxifloxacin to be a species of formula (I), and reinforces that the figure in Column 3 contains a clear error.⁵

C. Teva Cannot Avoid the POOS's Understanding of "Moxifloxacin"

Teva argues that the Court should blind itself to the uncontested record evidence of the ordinary meaning of moxifloxacin. Thus, Teva argues that the Court should ignore Dr. Taylor's testimony and the INN documents because they constitute "extrinsic evidence." D.I. 108 at 6-8.

This argument is a red herring. Teva does not dispute that moxifloxacin had an established

⁴ Teva fails to address the evidence that (1) use of "Me" to designate methyl in the structure in Column 3 tells the POOS that the line extending from the 3-position represents a bond to an inadvertently omitted substituent and (2) the MIC data informs the POOS that "moxifloxacin" does not have a 3-methyl. D.I. 93 at 10-12. Teva's response to the latter focuses on whether the compound in Column 3 in fact lacks antibacterial activity, but that misses the point. The evidence was that the POOS would expect it to lack antibacterial activity and would thus think the structure contained an error. Whether the compound actually kills bacteria is irrelevant.

⁵ The PTO recognized that moxifloxacin was part of formula (I), as it initially rejected the dependent claim to moxifloxacin on the basis that the '942 patent disclosed the antibiotics used in the claimed compositions. PTX 6 at BA001-2828; *see also* D.I. 93 at 13.

meaning to the POOS in September 1998 or that Dr. Taylor and the INN documents correctly identify that meaning. Teva simply says that the Court must ignore this ordinary meaning.

Teva fundamentally misapprehends the claim construction inquiry. As the Federal Circuit held in *Phillips*, “[t]he inquiry into how a [POOS] understands a claim term provides an objective baseline from which to begin claim interpretation.” 415 F.3d at 1313; *see also Honeywell*, 493 F.3d at 1361 (cited by Teva) (first ascertaining the ordinary meaning and then discussing whether that meaning had been overcome by a redefinition). To comply with that mandate, the Court must ascertain how the POOS would understand the technical term “moxifloxacin.” The notion that the Court should affirmatively disregard the established meaning of a claim term to the POOS runs directly contrary to *Phillips*.

Moreover, the evidence at issue is not the sort of extrinsic evidence about which *Phillips* expressed concern. There is no battle of the dictionaries here, nor are there competing experts offering conflicting ordinary meanings of a term. Everyone agrees that “moxifloxacin” had an ordinary meaning and agrees on what that meaning was. Indeed, Dr. Taylor’s testimony is precisely the kind of evidence *Phillips* deemed relevant, as it (1) establishes that “moxifloxacin” had a particular meaning to the POOS, and (2) explains how the POOS would view the patent’s chemistry issues. *See Phillips*, 415 F.3d at 1318.⁶ Likewise, the INN documents, by their very nature, provide the established meaning for “moxifloxacin.” An INN is an internationally-sanctioned name corresponding to one and only one compound, thereby ensuring that the POOS knows exactly which pharmaceutical compound is being used. *See* Tr. 57:11-61:16 (Taylor).

⁶ Teva’s suggestion that Dr. Taylor improperly reached his opinions by looking at Teva’s product is absurd. Moxifloxacin was well known long before Teva’s product. Dr. Taylor’s testimony that Teva’s product “doesn’t need to” contain a compound with the structure found in Column 3, D.I. 108 at 12, simply means that the product contains the compound known to the POOS as moxifloxacin and that it does not matter whether it contains other substances as well.

Teva also contends that Dr. Taylor, a chemist, cannot testify about the understanding of the POOS because he is not a microbiologist or ophthalmologist. D.I. 108 at 8. His testimony, however, was directed to the chemistry knowledge a microbiologist and/or ophthalmologist would have. It is uncontested he is qualified to opine on that subject, having taught introductory general and organic chemistry for years to future microbiologists and ophthalmologists. Tr. 51:17-52:12 (Taylor). And, in any event, Dr. Zhanel (a microbiologist) confirmed that the POOS would know that the structure in Column 3 contains an obvious error. Tr. 839:9-24 (Zhanel).

D. Teva Has No Evidence at All Regarding the 7-Position

Teva argues that it does not infringe because the patent defines moxifloxacin as a racemate. D.I. 108 at 13. Teva cites no evidence that the POOS would read the patent this way. There is none. The only evidence [REDACTED] is that the POOS would understand the compound in Column 3 to have S,S-stereochemistry. D.I. 93 at 14-15.

III. CLAIM 1 IS CORRECT AS WRITTEN

Finally, Teva argues that it is relevant that Alcon has not sought a formal correction of the '830 patent. D.I. 108 at 14. That has nothing to do with whether the POOS would understand moxifloxacin in claim 1 to carry its ordinary meaning. Unlike the cases Teva cites, there is no error in the claim to correct—it correctly says “moxifloxacin.” And there is no ambiguity about what “moxifloxacin” means: the compound commonly known as moxifloxacin.⁷

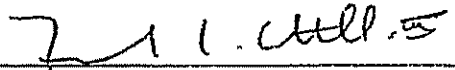
CONCLUSION

For the foregoing reasons, Alcon respectfully requests that the Court grant the relief requested in Alcon's Opening Brief.

⁷ Moreover, even if the claim contained an error, the standard for correction is more than met. See D.I. 93 at 14 n.8; *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1357 (Fed. Cir. 2003). There is no “reasonable debate” here: the sole evidence concerning the POOS's understanding of moxifloxacin is that it carries its plain meaning and that the structure in Column 3 contains an obvious error, and the file history is consistent with that interpretation.

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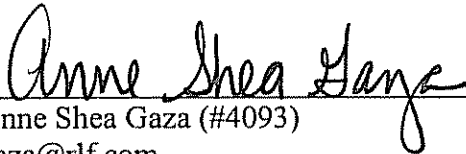
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